comprising determining whether said candidate compound re-radiates in the region of greater than about 360 nm up to about 400 nm upon exposure to sunlight, and, if so, rejecting said compound for use in said sunscreen.

REMARKS

Entry of the foregoing amendments, and reexamination and reconsideration of the subject application, pursuant to and consistent with 37 C.F.R. § 1.104 and § 1.112, and in light of the following remarks, are respectfully requested.

Claim 8 has been amended to clarify that a candidate compound that re-radiates at 360-400nm should not be included in the sunscreen.

Rejection under 35 U.S.C. 112, first paragraph

The rejection of claims 8-10 hereunder as failing to be supported by an adequate written description is respectfully traversed.

Claim 8 is directed to a method for making a sunscreen by examining the radiation re-emitted by the sunscreen. As amended, claim 8 clarifies that the compound so identified should not be included in the sunscreen. When the claim, even prior to amendment, is read in light of the specification, teaching that radiation in the 360nm to 400nm range is detrimental, there is no question that a compound that re-radiates in that range is undesirable.

Cited and incorporated by reference into the present application is a book edited by N. Lowe *et al.* entitled *Sunscreens* (see application at the top of pages two and ten). In the attached excerpt, at pages 274-275, it is described how "sunscreens" work: by converting the impinging energy into longer wavelength "(usually above 380 nm)" energy. The *Sunscreens* disclosure mentions that re-radiation may appear as heat if emitted in the IR region, as a fluorescence or phosphorescence if emitted in the visible region, or an even lower wavelength UV. Note also Fig. 7 at the top of page 275 of the excerpt.

Accordingly, it is well-known in the art that sunscreens of the type that absorb and re-emit radiation can emit the radiation at a number of different wavelengths. The *Sunscreens* book suggests that re-radiation at greater than 380 nm is not a problem for screening UV light, although there may be a cosmetic problem where the wavelengths in the visible spectrum, because most people do not want to fluoresce in the sunlight.

Applicants are not claiming that any specific compound re-radiates in the claimed region, although the *Sunscreens* excerpt clearly suggests that such compounds exist. In fact, the claimed method is aimed at rejecting candidate compounds that heretofore would have been found acceptable as sunscreens because of their utility for thwarting lower wavelength UV radiation. An identifying *characteristic* of a candidate compound, which *characteristic* is clearly appreciated in the art as a property of the compound, is re-radiation, and Applicants have refined those characteristics to include re-radiation in the upper UVA region, which spectral region heretofore was not appreciated as able to induce MMPs in human skin (note Figs. 6a, 6b, and 6c in the application). Based on the enclosed excerpts, the art is clearly able to measure the wavelength of energy re-radiated from a UV sunscreen.

> In this court's most recent application of the written description doctrine, it noted: "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required 'to recount his invention in such detail that his future claims can be determined to be encompassed within his original, creation.'" *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1330, 65 USPQ2d 1385, 1397 (Fed. Cir. 2003) (*citing Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991)).

Moba B.V. v. Diamond Automation Inc., 66 USPQ2d 1429, 1438 (CA FC 2003). Applicants' specification clearly shows they discovered that radiation in the 360-400 nm range (UVA) has detrimental effects on human skin. They need not

claim some structural aspect of some unknown rejectable candidate molecule. Rather, they can rely upon art-recognized techniques to determine the disclosed functional relationship between the properties of the compound and the radiation re-emitted. That is what Applicants disclose and what is claimed.

The same claims are also rejected as being non-enabled. The interpretation in the rejection of including the candidate compound that re-radiates at 360-400 nm in a sunscreen is not supported because the claims must be read in light of the specification, and the specification makes abundantly clear that radiation of that wavelength induces MMPs in human skin, and so such a compound should be rejected. Claim 8 has been amended to further clarify that such a compound is rejected.

Therefore, these rejections should be withdrawn.

Rejection under 35 U.S.C. 112, second paragraph

The rejection of claim 9 hereunder as lacking antecedent basis for "the UVA range" is respectfully traversed. The claim must be read in light of the specification, and it is well known what subregions of UVA, UVB, and UVC encompass UV radiation. (Note page 36 of the enclosed excerpt from *Sunscreens* ("The Solar Spectrum"); and pages one and three of the instant application.) The 360-400 nm range cited is inherently UVA, and would be understood as such to one of ordinary skill in the art. Accordingly, this rejection should now be withdrawn.

Double Patent Rejection

The rejection of claims 8-10 over claims 1 and 4 of the prior '630 patent (US 6,365,630) is respectfully traversed.

The '630 claim 1 does recite a composition that includes a UVA_1 blocker for 360-400 nm light. However, there are at least two reasons why such a claim does not render obvious the present claims.

First, claim 8 is not merely directed to a UV-blocking compound. Claim 8 is sufficiently broad to include any compound (such as a vehicle, emollient, colorant, odorant, etc.) in the sunscreen, and each of those compounds must be tested to determine whether they re-radiate at the specified wavelengths.

Second, once the sunscreen composition is on the skin, a compound that re-radiates at the specified wavelength produces radiation that is less likely to be blocked by the UVA_1 blocker of the '630 patent because it is in direct contact with the skin. Aside from the fact that the vast majority of sunscreen users apply an insufficient amount to meet the FDA monograph (*e.g.*, Chpt. 29 in *Sunscreens*) so that "leakage" of the UV radiation through the sunscreen occurs, at least the sun's light must pass through the entire layer of sunscreen. When a compound *within* the sunscreen layer (whether or not such a compound is present as a UV blocker) re-radiates in the UV region, there is substantially less chance that such radiation will be blocked from entering the skin.

The description by Applicants at page ten of the specification (not page nine as cited in the Office Action) of the above-discussed section of *Sunscreens* merely acknowledges that disclosure. As seen at page 275 and Fig. 7 of the enclosed excerpts from *Sunscreens*, those authors find a problem with re-radiation at 380-450 nm because of photochemical reactions with the sunscreen molecule, not because a portion of those wavelengths (380-400 nm) induce MMPs. Further, those authors attribute such cis-trans or keto-enol photo-isomerizations to cause a "mild shift in the λ_{max}" of the UV blocker, not to skin damage.

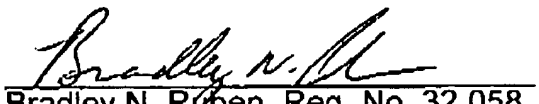
The existence of the composition of claim 1 of the '630 patent does not mean that any of those UV blocking compounds (or any of the adjuvant compounds in a commercial product covered by that claim) have been tested for re-radiation. Thus, practicing the '630 patent claim 1 does not necessarily infringe claim 8 of this application, and so does not render claims 8-10 obvious.

Accordingly, the present method claims would not have been obvious from the composition claimed in the '630 patent, and so this rejection should now be withdrawn.

Conclusion

In light of the foregoing amendments and remarks, withdrawal of all of the rejections, and further and favorable action, in the form of a Notice of Allowance, is believed to be next in order, and such actions are earnestly solicited.

Respectfully submitted,



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3 September 2003

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APPENDIX SHOWING MARKUPS OF AMENDMENTS

IN THE CLAIMS:

8. (Amended.) In the manufacture of a sunscreen by determining the absorbance of a candidate compound for particular wavelengths when the candidate compound is dispersed in a given medium, the improvement comprising determining whether said candidate compound re-radiates in the region of greater than about 360 nm up to about 400 nm upon exposure to sunlight, and, if so, rejecting said compound for use in said sunscreen.